

Agilik: A New Exoskeleton for Children Rehabilitation in Clinic or at Home

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IRCCS E. MEDEA

Outline

Background

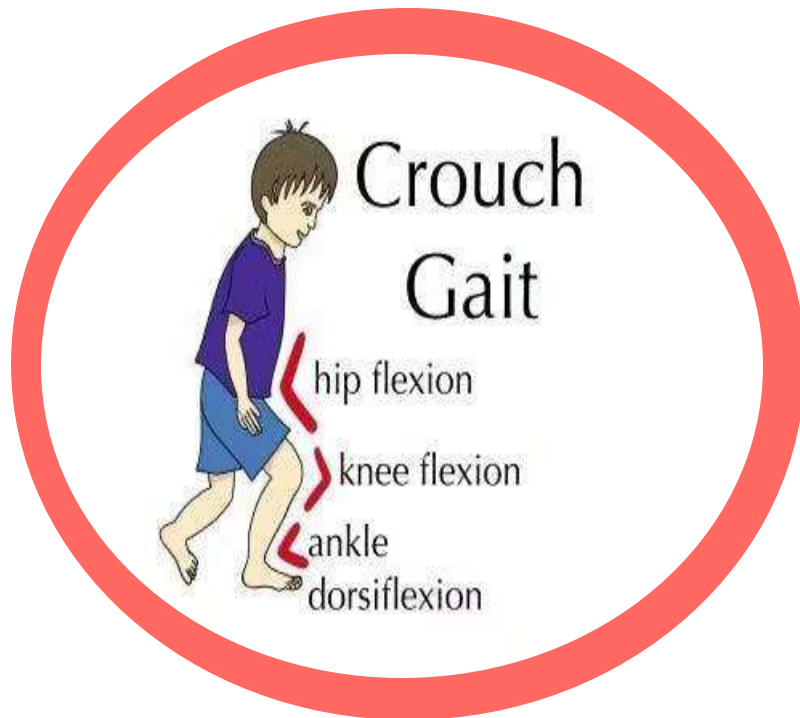
Protocol

Results

Conclusions

Cerebral Palsy

is a permanent, early-onset neurodevelopmental condition characterized by activity limitations resulting from impaired development of movement and posture. (Dan et al., 2025)



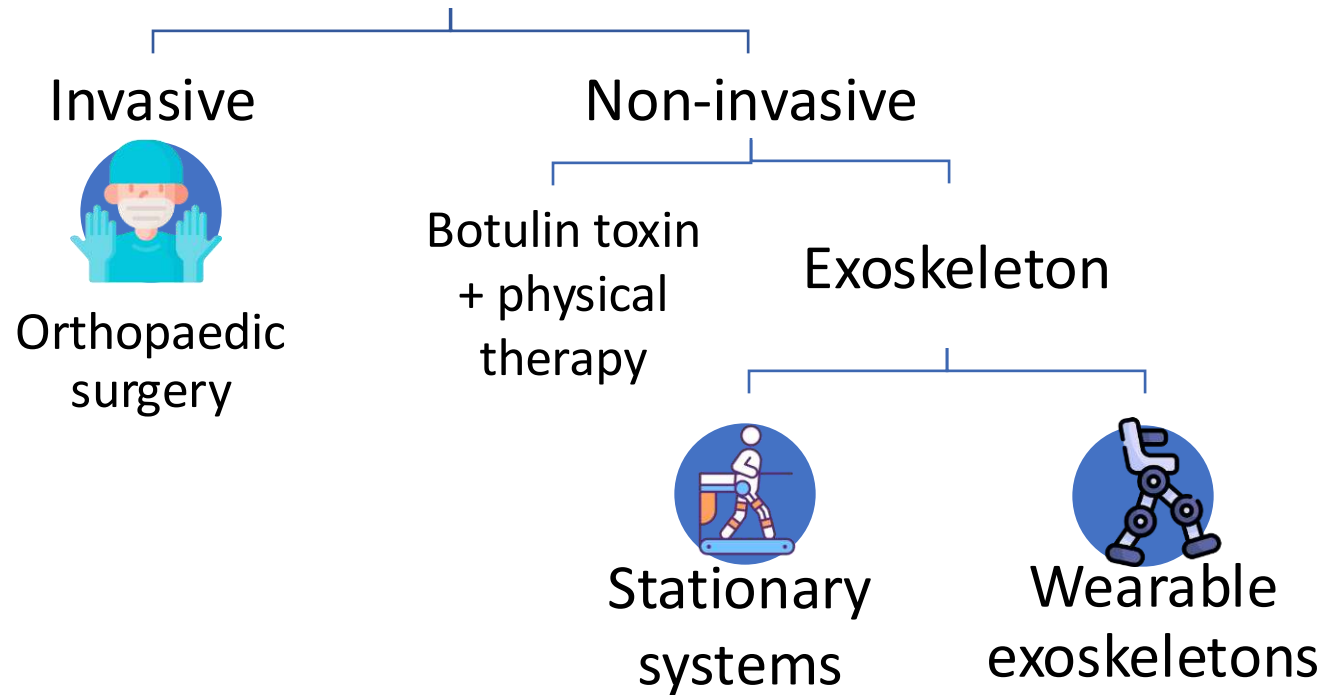
Crouch Gait

NEGATIVE IMPACTS!

- ✓ Increased energy expenditure
- ✓ Reduced walking autonomy



Treatments



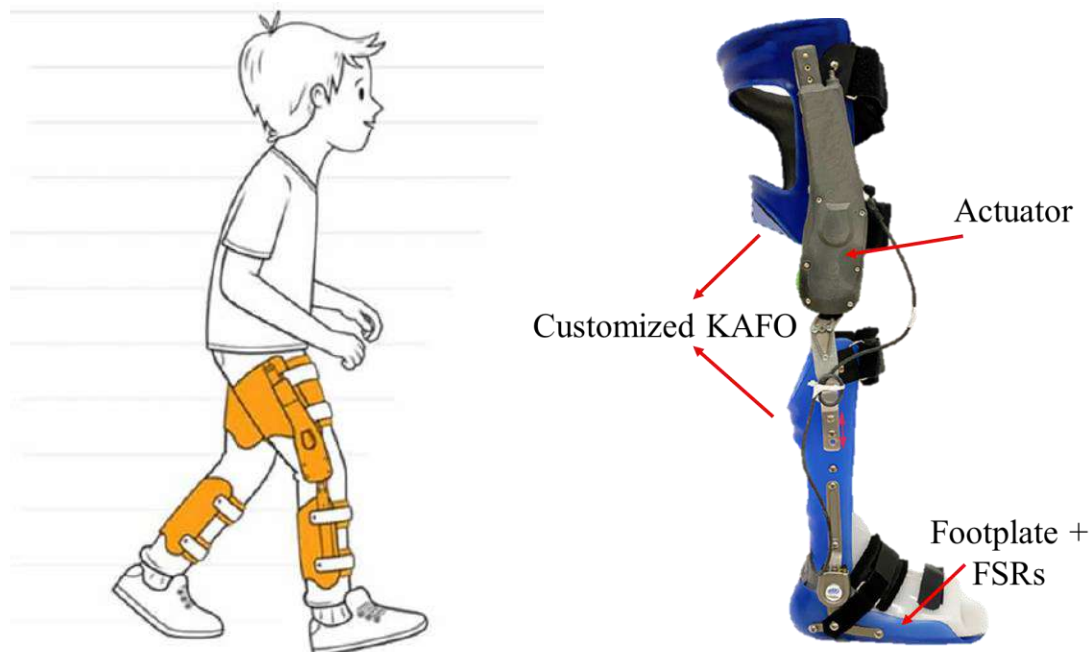
- ✓ In clinic
- ✓ Effectiveness
- ✓ Limited customization



- ✓ Customization
- ✓ Home use
- ✓ Very few studies
- ✓ Mainly prototype devices



The Device

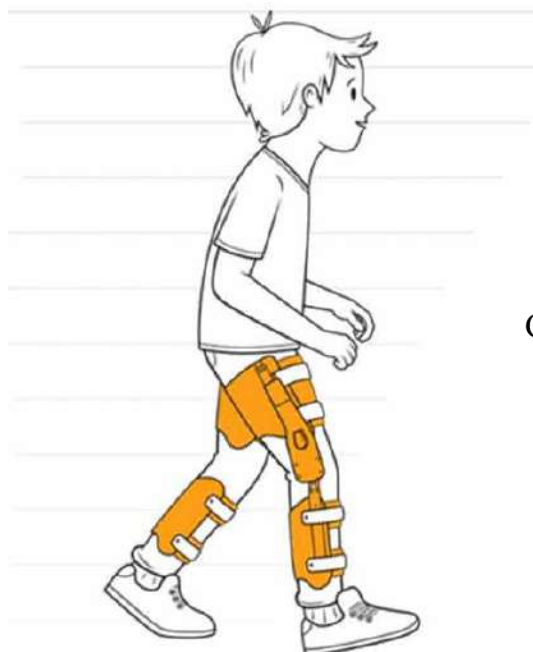


- **Class I** medical device
- **Active KAFO** that **assist or resist the movement** independently at each gait phase
- **Electro- mechanical actuators** at the knee joints
- **Magnetic encoder** in the gear box
- **Force Sensitive Resistors (FSRs)** in the footplate
- **Five states machine**

Agilik™

Manufactured by Bionic Power and distributed in Italy by Ro+Ten

The Device



STRENGTHS:

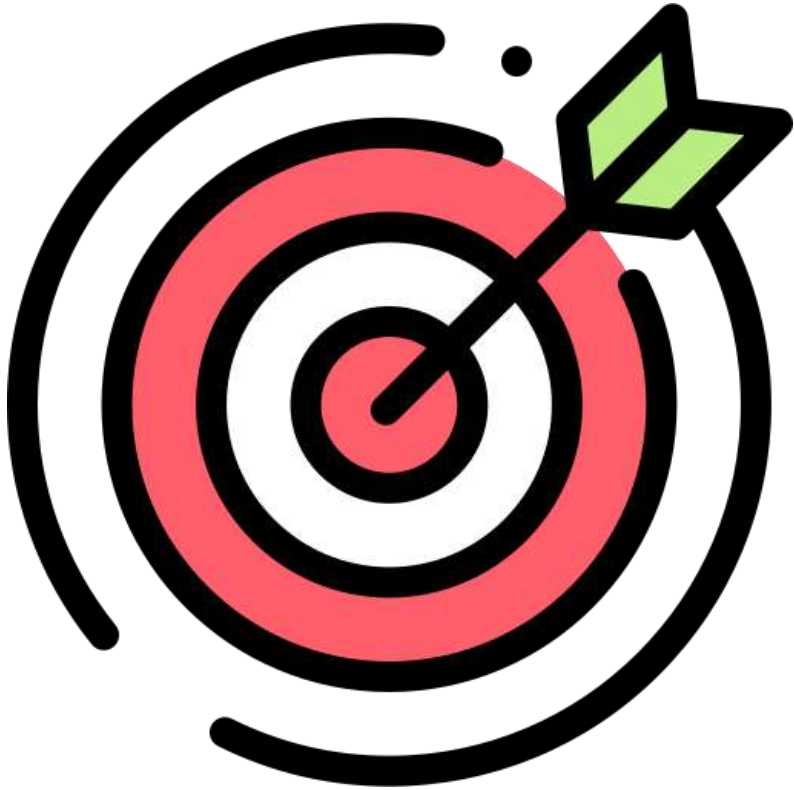
Customized KAFO

Wearable: both for clinic and home use



Agilik™

Manufactured by Bionic Power and
distributed in Italy by Ro+Ten



Aims of the work

To assess the assistive and rehabilitative effect of an **in-clinic training with Agilik**

To evaluate the performance of **Agilik in a home environment**

in children with crouch gait secondary to CP



March 2023: trial started



IRCCS E. Medea – Astrolab

Participants

INCLUSION CRITERIA

5 -17 years

Diagnosis of CP
with crouch
gait

Body weight
20 -125 kg

GMFCS level
I - III

$MAS \leq 2$

Able to
understand
simple
instructions



Background

Protocol

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T0 ASSESSMENT

Functional scales
(6MWT, 10MWT, MAS,
muscle length & ROM)

EXO FABRICATION

Casting for brace fabrication
Set-up and calibration of the
system

TRAINING

5 weeks
2 sessions/week
1h sessions
Indoor & outdoor
Uphill & downhill

T1 ASSESSMENT

Functional scales +
3D gait analysis on
the GRAIL system
with and without
Agilik

Participants

9 enrolled, 8 completed

Gender: 5 Males , 3 Females

Age: 11.9 (4.7) years old

GMFCS distribution



Ethics Committee approval: IRCCS E. Medea (Prot. N. 75/22—CE, 28/12/2022) · written informed consent obtained from all legal guardians

Registered on clinicaltrials.gov: NCT05746871

TRAINING

Ministero
dell'Università
e della Ricerca

Italiadomani
SOSTA E MIGLIA

PNC
Piano Nazionale per gli Investimenti
in Ricerca e Innovazione

**ASSESSMENT**

Ministero
dell'Università
e della Ricerca

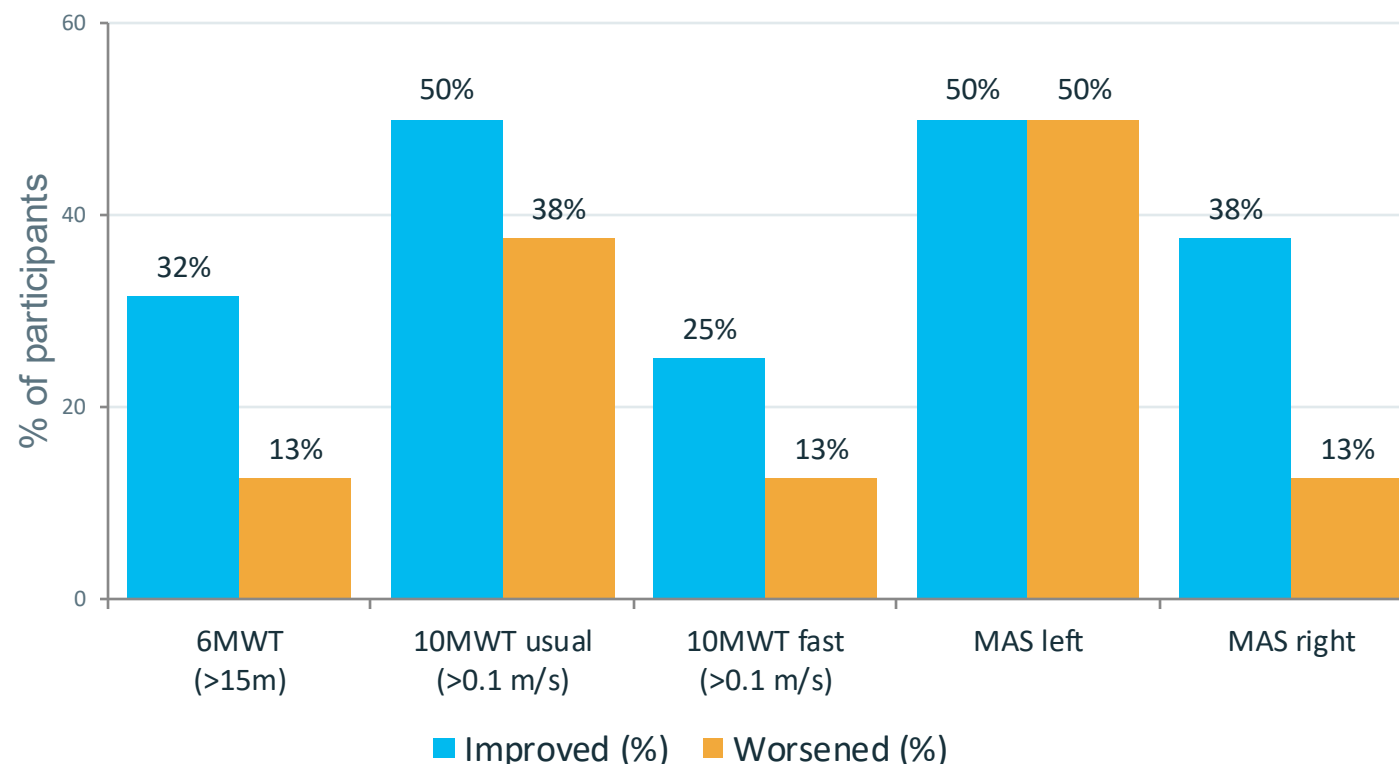
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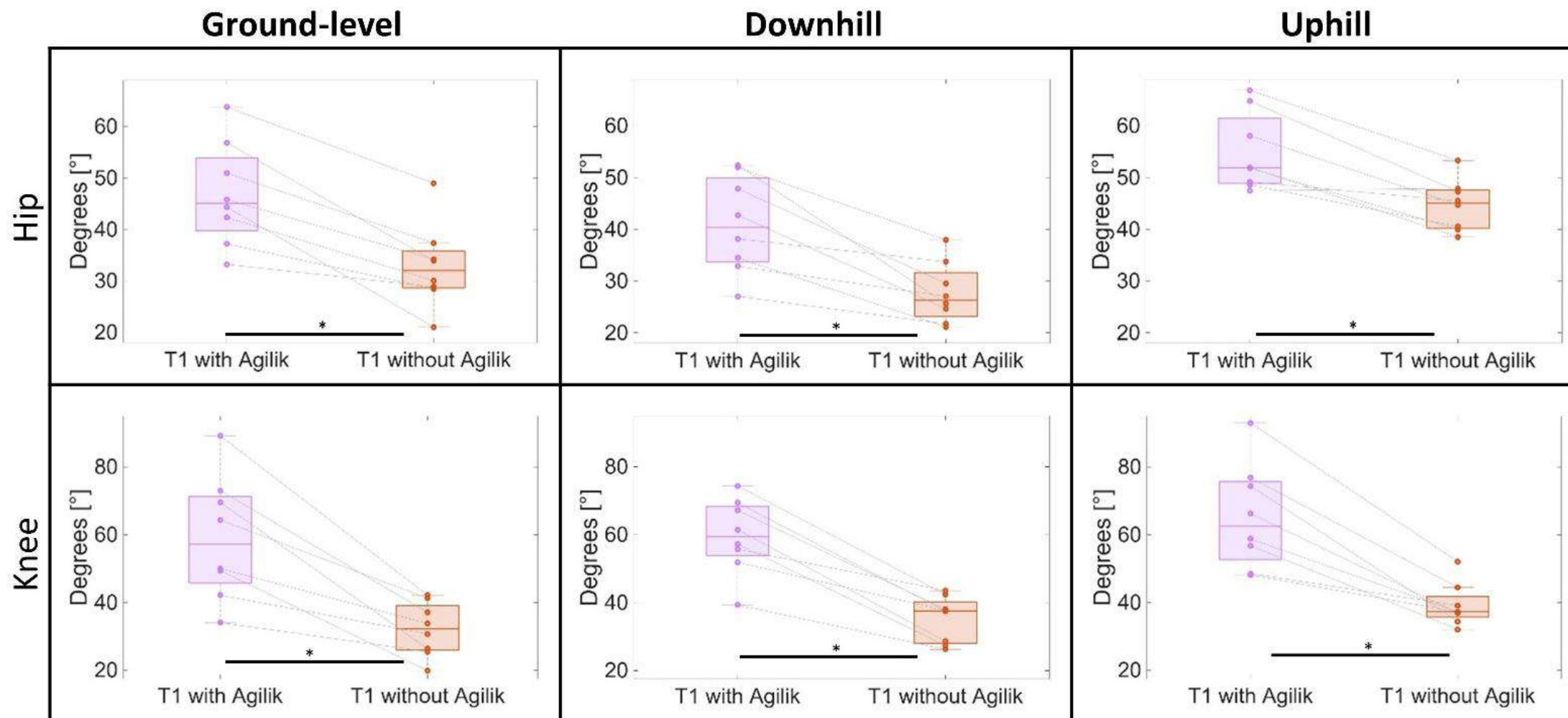
Rehabilitative effect

No statistically significant group-level change from baseline to post-intervention across all outcomes — *6MWT, 10MWT, MAS, muscle length & ROM, balance, GRAIL gait kinematics (all $p > 0.05$)*

MCID analysis: improvements outweigh declines



Assistive effect





Feasibility confirmed

Ten sessions of Agilik training were feasible and well tolerated in a paediatric clinical setting.



Clear, consistent assistive effect

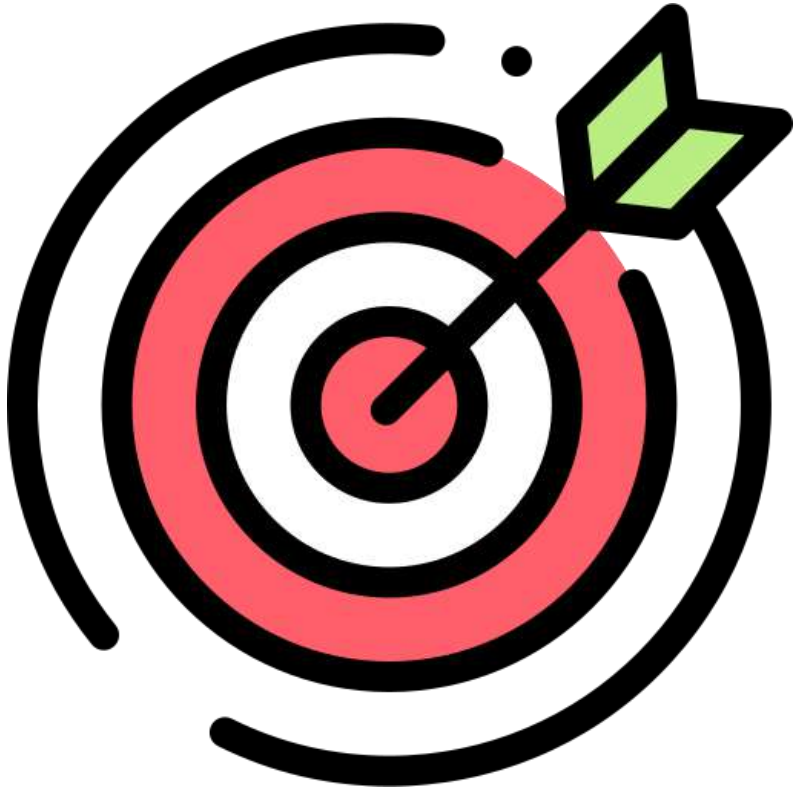
Real-time kinematic benefit at the knee and hip, across all walking conditions, including downhill gait, extending prior single-condition evidence.



Rehabilitative signal, not yet significant

Group-level change absent, but individual patterns tilt toward improvement, plausibly limited by short training duration and small sample.

Nossa et al, submitted to Frontiers in Medicine



Aims of the work

To assess the assistive and rehabilitative effect of an **in-clinic training with Agilik**

To evaluate the performance of **Agilik in a home environment**

in children with crouch gait secondary to CP



2024 multicentric Agilik@home trial initiated



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a Carattere Scientifico | IRCCS

Background

Protocol

Results

Conclusions

Protocol



**LA NOSTRA
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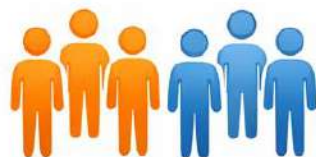
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40 children



6 clinical
centres

Ethics Committee approval: Comitato Etico Territoriale Lombardia 2 (ID R1927/24 – L2-131, 29/10/2024) · written informed consent obtained from all legal guardians

Registered on Clinicaltrial.gov: NCT06622655



**LA NOSTRA
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Enrollment



INCLUSION CRITERIA



CP and crouch



5-17 y.o.

GMFCS
I - III

Enrollment

T0

Assessment

TREATMENT

T1

Assessment

T2



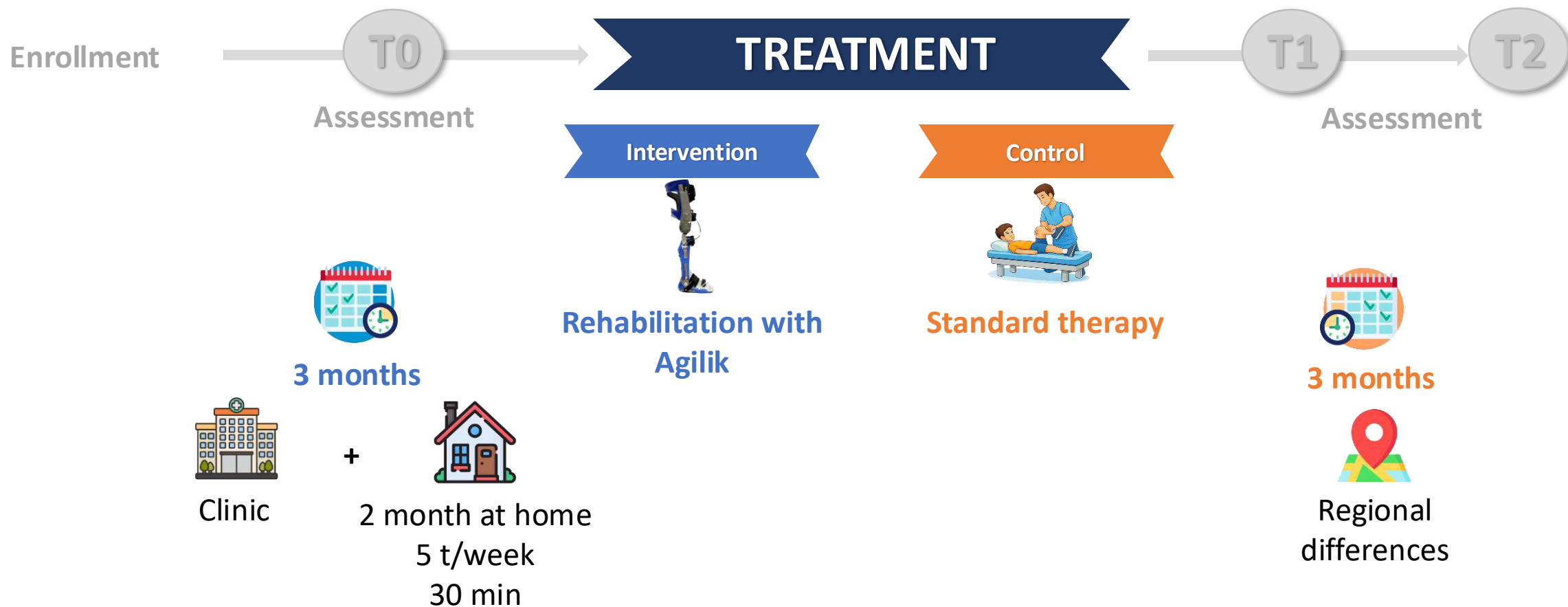
- 6MWT, 10mWT e GMFM



- MAS
- 3D gait analysis



- COPM



Enrollment

T0

Assessment

TREATMENT

Intervention

Control

T1

Assessment

T2



- 6MWT, 10mWT e GMFM

- MAS

- 3D gait analysis

- COPM

- SUS and TAM-3

- Parents interview

Nossa R et al (2026) Agilik@home: A randomized controlled trial protocol to evaluate the effects of home-based training with the Agilik powered KAFO in children with cerebral palsy and crouch gait. PLoS One 21(3): e0340877.

Participants

30 patients recruited

13 patients concluded the study

	N	Gender	GMFCS I\II\III	Age
Intervention	14	10M\ 4F	3\ 6\ 5	12.8 (2.6)
Control	16	11M\ 5F	4\ 7\ 5	10.8 (3.4)



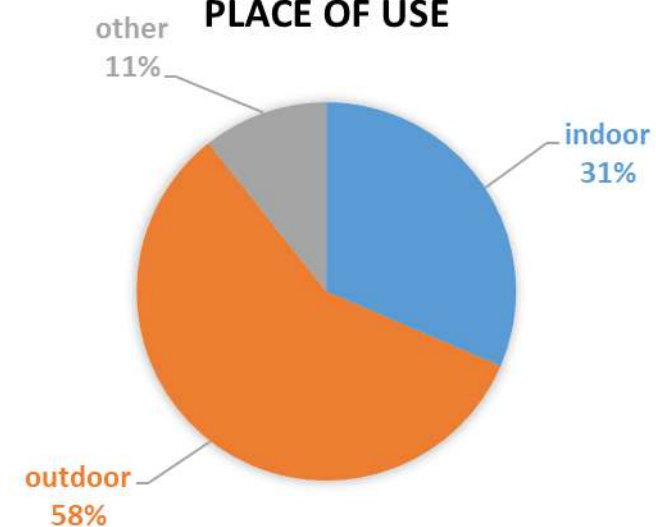
Agilik training and use



TIME OF TRAINING



PLACE OF USE



Conclusions and perspectives



Feasible, well tolerated

Consistent assistive effect in clinic

Good wear time with confident outdoor use at home



Small samples and short training leave rehabilitative effects not yet significant

Recruitment for the home trial is challenging, as the long protocol duration is demanding for families



Complete Agilik@home efficacy and usability analyses

Extend training duration and sample size

ACKNOWLEDGEMENT



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